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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,066	01/24/2001	Thomas R. Fuerst	4600-0293.20	7789
22918	7590	10/25/2006	EXAMINER	
PERKINS COIE LLP			PENG, BO	
P.O. BOX 2168				
MENLO PARK, CA 94026			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/769,066

Applicant(s)

FUERST ET AL.

Examiner

Bo Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 34, 37 and 38 is/are allowed.
- 6) ☒ Claim(s) 36 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 17, 2006 has been entered.
2. Claims 34 and 36-39 are pending and considered in this Office action.
3. Claims 36 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.
4. The new limitation of "at least 93% identical to SEQ ID NO: 15 and 16 over the entire length of the sequence" to an isolated polynucleotide of Claims 36 and 39 is not supported by the specification, therefore, is a new matter. Applicant is required to cancel the new matter in the response to this Office Action.

***Claim Rejections - 35 USC § 112, first paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Claim 36 is directed to an isolated polynucleotide selected from the group consisting of a polynucleotide encoding the polypeptides comprising an amino acid sequence at least 93% identical to SEQ ID NOs: 15 and 16 over the entire length of the sequence.

8. Because of the structure limitation, the scope of claim 36 encompasses an extremely large number of polynucleotides. Seven percent variation of 549 amino acid carboxy-terminal end of HEV ORF 2 is approximately 38 amino acid residues. The math reveals that 7% amino acid substitutions of 549 amino acid carboxy-terminal end of HEV ORF 2 can result in many millions of possible permutations. If 38 residues (or sites) are variously changed by any one of 20 amino acid residues along the 549 amino acid of ORF2 sequence, the number of possible change at permutation is  $20^n$ , when  $n=38$  (sites), which results in an extremely large number of variations. For example, one substitution by one of 20 amino acids would result in 20 variations; two substitutions by one of 20 amino acids at either site would result in 400 variations; three would result in 8,000 variations, etc. Thus, the scope of claim 34 encompasses an extremely large number of a polynucleotide encoding the polypeptides having 7% variation of SEQ ID NOs: 15 and 16. As a result, the claim 36 reads on a polynucleotide with no defined structure and the specification does not reasonably convey possession of these undefined polynucleotides. The specification has only disclosed isolated nucleic acids of HEV Burma and Mexico strains that encode an amino acid sequence of SEQ ID NOs: 15 and 16, but not all nucleic acids degenerated

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from amino acid sequence of SEQ ID NOs: 15 and 16, nor any undefined nucleic acids that encode the polypeptides 7% identical to an amino acid sequence of SEQ ID NOs: 15 and 16.

9. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/ function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. There is no indication that Applicant was in possession of all polynucleotide as broadly claimed.

Vas-Cash Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acids claimed. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co.*

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Ltd., 18 USPQ2d 1016. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

10. Claim 36 is further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

11. The scope of the claims must bear a reasonable correlation with the scope of enablement. See *In re Fisher*, 166 USPQ 18 24 (CCPA 1970). "It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." *Colbert v. Lofdahl*, 21 USPQ2d, 1068, 1071 (BPAI 1992). The structural limitations of claim 34 clearly cover an extremely large number of undefined polynucleotides as discussed above, which encode polypeptides having 7% variation of SEQ ID NOs: 15 and 16. In view of the empirical and unpredictable nature of the art and lack of guidance with respect to appropriate modifications, one skilled in the art would have to make and test all undefined polynucleotide that meet the structural limitations to determine which also have the function of the polypeptide of SEQ ID NOs: 15 and 16. This amount of experimentation would be undue. Therefore, the specification, while being enabling for a polynucleotide encoding the polypeptide of SEQ ID NOs: 15 and 16 does not reasonably provide enablement for a polynucleotide encoding the polypeptides comprising an amino acid sequence at least 93%

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identical to an amino acid sequence of SEQ ID NOs: 15 and 16.

*Remarks*


12. Claims 34, 37 and 38 are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Bo Peng, Ph.D.  
10/19/06

  
**MARY E. MOSHER, PH.D.**  
**PRIMARY EXAMINER**